DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Bruce Lester
Vice President, Research and Development
SterilMed, Inc.
11400 73rd Ave. North
Minneapolis, Minnesota 55369

NOV 1 2004

Re: K012571 – Supplemental Validation Submission
Trade/Device Name: Reprocessed Ultrasonic Scalpel (See enclosed list)
Regulatory Class: Unclassified
Product Code: NLQ
Dated: August 7, 2001
Received: August 9, 2001

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on November 7, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Reprocessed Ultrasonic Scalpel Models found to be Substantially Equivalent:

1. Ethicon, HDH05
2. Ethicon, HSH05
3. Ethicon, HBC05
4. Ethicon, HC325
5. Ethicon, DH010
6. Ethicon, DSH10
7. Ethicon, DBC10
8. Ethicon, DH105
9. Ethicon, DH145
10. Ethicon, HC105
11. Ethicon, SH105
12. Ethicon, SH145

Indications for Use

510(k) Number (if known): K012571

Device Name: Reprocessed Harmonic Scalpels

Indications For Use:

The Reprocessed Harmonic Scalpels are intended for use in soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecological and other endoscopic procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K012571

K012571

NOV 0 7 2001

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis, MN 55369
Ph: 763-488-3400
Fax: 763-488-3350

Date Prepared: August 7, 2001

Trade Name: Reprocessed Harmonic Scalpels

Classification Name: Electrosurgical cutting and coagulation device and Accessories

Classification Number: 21 CFR 878.4400

Product Code: LFL

Predicate Device(s): The reprocessed harmonic scalpel is substantially equivalent to the Harmonic Scalpel Hs2 Blade (K941897), manufactured by Ethicon (formerly Ultracision); Reusable Laparosonic Blade System (K930352), manufactured by Ethicon (formerly Ultracision); and the counterpart devices from the original manufacturer.

Device Description: Harmonic scalpels are part of an ultrasonic system and are intended to be used in soft tissue surgery for simultaneous cutting and hemostasis. The system consists of a generator/foot switch, handle, connecting hose, and a scalpel blade. Only the handle and scalpel blade are reprocessed. The generator/foot switch and hose components of the device are not included as part of this submission.

Harmonic scalpels can be manufactured using aluminum with a nickel chrome alloy edge or a titanium alloy (with or without a coating.) These scalpels are available in a variety of lengths, outer circumferences, angles, and sharpness.

Intended Use:

The reprocessed harmonic scalpels are intended for use in soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecological and other endoscopic procedures.

Functional and Safety Testing:

Representative samples of reprocessed harmonic scalpels underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products reprocessed.

Conclusion:

The reprocessed harmonic scalpel is substantially equivalent to Harmonic Scalpel Hs2 Blade (K941897), manufactured by Ethicon (formerly Ultracision); Reusable Laparosonic Blade System (K930352), manufactured by Ethicon (formerly Ultracision); and the counterpart devices from the original manufacturer. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.